IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	REDACTED - PUBLIC VERSION C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF "SHAM LITIGATION" RELATING TO THE CAPSULE CASES

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I. INTRODUCTION

Defendants respectfully submit this reply in further support of their motion for summary judgment dismissing the Purchaser Plaintiffs' and Impax's sham litigation claims concerning the Capsule Cases.[1] Teva has not alleged that the Capsule Cases were shams.

Plaintiffs' sham litigation claims are based on disputes over the construction of two claim terms, "co-micronized" and "solid surfactant." Purchaser Plaintiffs Br. at 2-3 (D.I. 411 in C.A. 05-340); Impax Br. at 6-7 (D.I. 531 in C.A. 03-120). As set forth in Defendants' Opening Brief and in this brief, there were reasonable grounds to dispute the claim constructions. Defendants' constructions were supported by the ordinary meaning, specification, and credentialed experts in the field, and presented reasonable grounds for litigation.

There is nothing remarkable about claim construction disagreements in general and nothing unique about the claim construction dispute at issue here. A court's rejection of a claim construction argument does not mean that the proponent of the construction was engaging in "sham litigation" or taking an objectively baseless position.

Plaintiffs have not come forward with clear and convincing evidence that Defendants' claim constructions positions were "objectively baseless" under *Professional Real Estate Inventors, Inc. v. Columbia Pictures, Inc.*, 509 U.S. 49, 51 (1993) ("*PRE*"). At most, they address issues that presented fair grounds for litigation in the Capsule Cases. That is not enough to avoid summary judgment.[2]

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[1] The Capsule Cases involved U.S. Patent No. 4,895,726 (the "'726 patent"; DJA-Reply 140) and was litigated in the U.S. District Court for the Northern District of Illinois. Teva Pharmaceuticals is the successor in interest to Novopharm Industries, Ltd, a defendant in the Capsule Cases.

[2] *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254-55 (1986) ("[I]n ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden" and thus in all civil cases in which the "clear

II. CASE LAW DEFEATS IMPAX'S ARGUMENTS ON THE ALLEGED INADEQUACY OF DEFENDANTS' PRE-SUIT INVESTIGATION.

Impax asks the Court to draw a negative inference from the Defendants' reliance on privilege with respect to their pre-suit investigation. The Purchaser Plaintiffs do not seek such an inference with respect to the Capsule Case against Teva.[3]

The recent Federal Circuit decision *Dominant Semiconductors Sdn. Bhd. v. Osram GmbH*, 524 F.2d 1254 (Fed. Cir. 2008) defeats Impax's argument. In *Dominant*, as here, an antitrust plaintiff tried to satisfy the "objective prong" of the *PRE* test by challenging the adequacy of the defendant's pre-suit investigation. The Federal Circuit unequivocally rejected that theory as having "nothing to do" with the relevant issues. *Id.* at 1264.[4] Under *Dominant*, Impax's arguments concerning the adequacy of Defendants' pre-suit investigation have absolutely "nothing to do" with the "objective reasonableness" prong of *PRE*.[5]

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and convincing" standard applies, the "clear-and-convincing standard of proof should be taken into account in ruling on summary judgment motions); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003); *see, e.g., Dominant Semiconductors Sdn. Bhd. v. Osram GmbH*, 524 F.3d 1254 (Fed. Cir. 2008) ("[t]o survive summary judgment, the party challenging . . . statements [regarding infringement] must present affirmative evidence sufficient for a reasonable jury to conclude that the patentee acted in bad faith, in light of the burden of clear and convincing evidence that will adhere at trial.").

3 In the Teva case, before filing suit, Abbott's counsel asked Teva for information regarding its proposed product but did not receive it within the 45-day period provided by the Hatch-Waxman Act. Teva was in exclusive control of that information, but chose not to provide it until after the statutory deadline. The fact that Teva withheld the requested information, in and of itself, provides an objectively reasonable basis to file suit. *Hoffmann-LaRoche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

4 Defendants discuss the *Dominant* opinion more fully in their Reply Brief In Support of Defendants' Motion for Summary Judgment Dismissing Plaintiffs' Sham Litigation and Walker Process Claims Relating to the Tablet Cases, and incorporate it herein.

5 [redacted]

Moreover, courts do not allow a "negative inference [to] arise from the assertion of the [attorney-client] privilege." *In re Terazosin Hydrochloride Antitrust Litig*, 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1345 (Fed. Cir. 2004) ("There is precedent for the drawing of adverse inferences in circumstances other than those involving attorney-client relationships . . . . However, the courts have declined to impose adverse inferences on invocation of the attorney-client privilege."); *Parker v. Prudential Ins. Co. of Am.*, 900 F.2d 772, 775 (4th Cir. 1990) ("[A] client asserting the privilege should not face a negative inference about the substance of the information sought") (cited by Federal Circuit in *Knorr-Bremse*).[6]

III. DEFENDANTS' CONSTRUCTION OF THE CLAIM TERM "CO-MICRONIZED" WAS OBJECTIVELY REASONABLE.

The Purchaser Plaintiffs argue that "there is no question today who was right and who was wrong." Purchaser Plaintiffs Br. at 3 (D.I. 411 in C.A. 05-340) This misses the point. The question before the Court is not one of deciding which party was right or wrong. Rather, the question is whether Defendants' proposed claim construction was based on reasonable grounds.

A. There is Objective Support for the Plain Meaning of "Co-Micronized."

The key issue in the Capsule Cases was the claim construction for the term "co-micronized." As set forth in Defendants Opening Brief at 13-16, Defendants' proposed construction of "micronized with or together" was based on the ordinary meaning and accepted

[redacted]

6 Impax cites *In re WellButrin SR Antitrust Litig*, 2006 US Dist LEXIS 9687 (E.D. Pa. Mar. 9, 2006) and *Hoffman-LaRoche v. Genpharm Inc*, 50 F. Supp. 2d 367 (D.N.J. 1999) in support of its positions. Both cases were prior to *Dominant* and both were in the context of a motion to dismiss. Also, neither case implicates privilege.

claim construction principles prohibiting the importation of limitations from the specification into the claims. The ordinary meaning of the term was acknowledged by [redacted] both district court judges, and the Federal Circuit.[7, 8]

"Co-micronized" was ultimately construed as "fenofibrate and a solid surfactant have been micronized together ***in the absence of other excipients***." *Abbott Labs*, 323 F.3d at 1330. The added requirement that co-micronization occur in the absence of other excipients is subject to reasonable dispute. Notably, the added requirement is not part of the ordinary meaning nor is it stated anywhere in the specification.

In arguing that it was unreasonable for Defendants to propose a construction without the "absence of other excipients" requirement, Plaintiffs rely on a statement in the specification describing co-micronization as "the micronization of an intimate mixture of fenofibrate and a solid surfactant." Impax Br. at 22 (D.I. 531 in C.A. 03-120); Purchaser Plaintiffs Br. at 4 (D.I. 411 in C.A. 05-340); '726 patent, DJA-Reply 142, at col. 1, ll. 35-38. Plaintiffs equate the word "intimate" with the phrase "absence of other excipients." However, the specification's use of the word "intimate" does not necessarily exclude all other ingredients.

[redacted]

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7 Citations to "DJA-Reply" refer to pages of Defendants' Joint Appendix – Reply, filed concurrently with this brief.

8 [redacted] *Abbott Labs. v. Novopharm Ltd*, 2002 WL 433584, at *6 (N.D. Ill. March 20, 2002); *Abbott Labs. v. Impax Labs. Inc*, 2003 WL 1563426, at *5 (N.D. Ill. March 26, 2003); *Abbott Labs. v. Novopharm Ltd*, 323 F.3d 1324, 1330 (Fed. Cir. 2003).

[redacted] An intimate gathering, for instance, rarely refers to just two people. [redacted] Similarly, Defendants' belief that "intimate" mixture was not limited to fenofibrate and SLS in the absence of everything else was reasonable.

Plaintiffs find significance in the fact that two district judges and three Federal Circuit judges rejected Defendants' proposed construction of the term "co-micronized fenofibrate." Purchaser Plaintiffs Br. at 3 (D.I. 411 in C.A. 05-340); Impax Br. at 3 (D.I. 531 in C.A. 03-120). But as Defendants' have demonstrated in their Opening Brief and above, judicial rejection of a position does not make it "objectively baseless" under *PRE*.

B. Applicants Did Not Limit the Term "Co-Micronized" During Reexamination.

The Purchaser Plaintiffs (but not Impax) further argue that Defendants' construction is baseless because the meaning of the term "co-micronized" was allegedly narrowed by a Response submitted to the Patent and Trademark Office during the Reexamination proceeding of

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9 [redacted]

the '726 patent. Purchaser Plaintiffs Br. at 6 (D.I. 411 in C.A. 05-340). The Purchaser Plaintiffs are wrong.

The Response in question was retracted (DJA-Reply 153-154), replaced with a corrected submission (DJA-Reply 155-168) that did not contain the statement on which the Purchaser Plaintiffs now rely, and the Patent Office expressly stated that it did not consider the original Response.[10] A reasonable competitor would not rely upon the withdrawn response.[11] *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (explaining that if the applicant mistakenly disclaims coverage of the claimed invention, the applicant can retract his statements and amend the file to correct the error). Purchaser Plaintiffs cite to no authority that supports their argument.[12] It was objectively reasonable for Defendants to contend that the withdrawn Response was not a disclaimer.

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10 *See* Chorush Decl. Exh. H ("The examiner will consider only the Patent Owner's statement filed April 6, 2001 [the revised statement]").

11 [redacted] argumentative statements in a withdrawn submission are not a clear and unmistakable surrender of subject matter and cannot be used to support a disclaimer based on the prosecution history. *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005).

12 [redacted]

IV. DEFENDANTS' CONSTRUCTION OF "CO-MICRONIZED" DID NOT EMCOMPASS THE PRIOR ART.

A. Purchaser Plaintiffs Misread Table II in the '726 Patent.

The Purchaser Plaintiffs – but neither Teva nor Impax, the alleged infringers – argue that the Capsule Cases were baseless because Defendants' "preposterous" claim construction encompassed formulations that are distinguished in Table II of the '726 patent. Purchaser Plaintiffs Br. at 2 (D.I. 411 in C.A. 05-340). This argument is an attempt to create a controversy where none exists.

Table II in the '726 patent, reproduced below, compares the dissolution rates of formulations consisting of: 1) pure micronized fenofibrate, 2) co-micronized fenofibrate and SLS, and 3) separately micronized and then mixed fenofibrate and SLS.

TABLE II

	VALUE OF THE T 50% TIMES (in minutes)		
INGREDIENTS	A	B	C
Micronized pure fenofibrate	37.165	37.165	0
Fenofibrate + 1% of NaLS	18.01	8.62	−52.14

TABLE II-continued

	VALUE OF THE T 50% TIMES (in minutes)		
INGREDIENTS	A	B	C
Fenofibrate + 3% of NaLS	23.75	12.68	−46.61
Fenofibrate + 5% of NaLS	20.35	11.425	−43.86
Fenofibrate + 7% of NaLS	14.5	10.76	−25.79

Notes
A mixture of micronizates
B co-micronization of the mixture of ingredients
C variation $\frac{B - A}{A} \times 100$ (in %)

See '726 Patent, DJA-Reply 143, col. 3, l. 62 to col. 4, l. 13.

The Purchaser Plaintiffs argue that the distinguished "non-co-micronized and mixed" (shown in Table II as "mixture of micronizates") formulations are the same as Teva's product. The Purchaser Plaintiffs are mistaken. As is clear from the table itself in the column labeled "Ingredients," the formulations being tested in Table II contain only fenofibrate and SLS, and were not made using a wet granulation manufacturing process, [redacted] Purchaser Plaintiffs Br. at 10 (D.I. 411 in C.A. 05-340).

[redacted]

In view of the evidence, Purchaser Plaintiffs' argument falls apart. There is no clear and convincing evidence that Defendants' construction of "co-micronized" in the Capsule Cases encompassed the prior art.

B. Purchaser Plaintiffs Mischaracterize Dr. Goldberg's Deposition Testimony.

[redacted]

13 [redacted]

[redacted]

Column 2 of the '726 patent describes a procedure for preparing compositions of the invention. *See* '726 patent, DJA-Reply 142, at col. 2, ll. 5-20. The first step of that procedure requires "intimately mixing and then co-micronizing the fenofibrate and the solid surfactant." *Id.* at col. 2, ll. 9-10. [redacted] The procedures of column 2 include several processing steps, including "adding lactose . . . ," "converting the whole . . . ," "drying the granules . . . ," "grading the granules," and "adding polyvinylpyrrolidone and magnesium stearate . . . ." '726 patent, DJA-Reply 142, at col. 2, ll. 5-

14 [redacted]

20. This set of process steps was not included in making the formulations of Table II. The formulations of Table II were different and would not have been encompassed by Defendants' construction of the claim term "co-micronized."

V. DEFENDANTS' CONSTRUCTION OF THE CLAIM TERM "SOLID SURFACTANT" WAS OBJECTIVELY REASONABLE.

The Purchasers Plaintiffs and Impax argue that the Capsule Cases were a sham because Defendants' construction of "solid surfactant" was objectively baseless. The Purchaser Plaintiffs and Impax attempt to frame this as a factual issue. However, the disagreement is over the construction of the claim term. In the Capsule Cases, Defendants relied upon the term's ordinary meaning and argued that "solid surfactant" should be construed to mean a surfactant that is "solid at standard temperature and pressure and in a formulated dosage form."

[redacted]

15 [redacted]

[redacted] However, the characteristics of SLS in the final product are sufficient to prove infringement, regardless of its characteristics in an interim stage of the manufacturing process. *See Applera Corp v. MJ Research, Inc.*, 311 F. Supp. 2d 263, 272-273 (D. Conn. 2004) ("Where, as here, a claim element of a product patent does not incorporate a manufacturing process, the process of manufacture is legally irrelevant ... for purpose of a literal infringement analysis.").

VI. IMPAX'S ARGUMENT THAT THE SOLID SURFACTANT PARTICLES GET LARGER IS SPECIOUS.

Impax also argues, for the first time in this litigation, that Defendants could not reasonably have expected to prevail in the Capsule Cases because SLS actually gets bigger when mixed with fenofibrate and dried. Impax Br. at 23 (D.I. 531 in C.A. 03-120).

To the contrary, Defendants contended [redacted] that the size of the SLS particle (and the fenofibrate particles, for that matter) should be compared at the beginning and the end of the manufacturing process. It would make no sense to measure particle sizes at some intermediate point as Impax now argues. [redacted]

Impax's newly manufactured argument is not clear and convincing evidence that it was objectively baseless for Defendants to contend the SLS in Impax's product was a "solid surfactant."

VII. CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion for summary judgment and find that the Capsule Cases were not "sham" litigations.

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